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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,370	07/08/2003	Neil David Hammond Raven	1581.0990001/RWE/VSR	7846

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EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/614,370

Applicant(s)

RAVEN ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 12-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/19/06</u> <u>12/65</u> <u>df-c5</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-35 are pending.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on July 8, 2003; December 16, 2003; January 16, 2005; April 25, 2005; and June 19, 2006, were received. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Preliminary Amendment

The Preliminary Amendment filed December 16, 2003, has been received and entered.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-11 and 31-35 in the reply filed on April 25, 2006, is acknowledged. The traversal is on the ground(s) that there would be no burden to examine claims 26-27 along with Group I. This is not found persuasive because the method of Group I does not require a buffering agent to be present per se. Further, there is one way distinctness between the product and method wherein the method as stated above does not require a buffering agent. Thus, the restriction is deemed proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 25, 2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shenoy et al (US 5756678), cited on enclosed PTO-892 Form in view of Daniel et al (D1), cited on enclosed copy of PTO-1449 Form filed June 19, 2006.

Claims are drawn to a method for inactivating a transmissible spongiform encephalopathy (TSE) agent (i.e. prion) comprising exposing the agent to a thermostable proteolytic enzyme.

Shenoy et al teach exposing an infectious prion agent (i.e. TSE) to proteolytic enzyme, note title of invention, column 2, lines 30-35, column 3, lines 50-65, column 9, lines 15-25, and column 15, lines 10-45.

Daniel et al teach thermophilic proteolytic enzymes from Archae bacteria including Bacillus bacteria. Note the entire 27 pages wherein each of temperature and pH are disclosed in Tables 1 and 2.

The claims differ from Shenoy et al in that thermophilic proteolytic enzymes are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to select for thermophilic proteolytic enzymes for exposing an infectious prion TSE agent disclosed by Shenoy et al to the enzymes disclosed by Daniel et al. Clearly one of skill would have expected successful results and would have been motivated to select for these enzymes because they are more stable. Proteolytic enzymes are well known to deactivate TSE and one of skill would have been motivated to select these enzymes for this purpose. To select for thermostable enzymes having stability at higher temperatures is clearly within the purview of an artisan, and Daniel et al disclose their enzymes work above 40 degrees C and also at 75 degrees C which is within the claimed ranges. To select for alkaline pH is also within the purview of a skilled artisan. To select for subtilisin derived from Bacillus bacteria or

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MC-A, MC-3 and MC-4 is an obvious modification of the cited prior art . In the absence of convincing evidence to the contrary the claims are prima facie obvious over the cited prior art.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
June 24, 2006